

FD ID: FD1929

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**Project Title: Comparing DEcolonization approaches For the reduction of surgical site INFections – the DEFINE study**

**Background/Rationale: Research Question:** The goal of our research is to reduce surgical-site infections (SSIs), a leading cause of healthcare-associated infections (HAIs) associated with significant morbidity and mortality. Pre-operative bathing as well as decolonization of nasal bacteria (particularly *Staphylococcus aureus*) have been recommended strategies to reduce SSIs and are widely used in clinical practice. However, the optimal decolonization strategy – the strategy that is most effective, preferred by patients, and associated with fewest implementation barriers – is uncertain.

**Question: Which of two widely used nasal decolonization approaches is optimal – mupirocin (an antibiotic) or povidone iodine (an antiseptic)?** Answering this question is important given concerns about mupirocin resistance and the potential for some patients to find the decolonization procedure burdensome (i.e., requires application in the nose twice daily for 5 days before surgery). Povidone iodine (PVI) is relatively new, is applied only on the day of surgery and risk of resistance to an antiseptic is very low. Although PVI has become widely used given these favorable features, data on its effectiveness compared to mupirocin is very sparse.

A second issue in SSI prevention is the use of pre-operative whole-body bathing (either with chlorhexidine [CHG] or soap and water), often in conjunction with intranasal decolonization.

**Question: Although CHG bathing is widely used, is it more effective than soap and water bathing alone for preventing SSIs?** This question is important to answer as patients may have allergies to CHG, have to source the product, pay for it, and find the CHG bathing procedure burdensome as CHG must dry fully on skin for maximal decolonization. Although CHG is widely used, data on its effectiveness compared to soap and water alone are lacking.

Despite widespread use of varying combinations of these strategies to prevent SSI, the relative effectiveness of decolonization strategies in preventing SSI have not been established. This lack of evidence is a major gap in the field that hinders our ability to reduce the burden of SSIs in the large number of patients who undergo surgery every day.

To address this, we will conduct a multicenter two-by-two factorial individual randomized controlled trial (RCT) to-

**Specific Aim 1:** Compare the effectiveness of two intranasal decolonization methods (mupirocin and PVI) and two approaches to body bathing (CHG and soap and water) in patients undergoing elective orthopedic, cardiovascular, thoracic and neurosurgical procedures on reducing the incidence of SSI, SSI due to *S. aureus*, and readmission or admission.

**Specific Aim 2:** To evaluate implementation of the decolonization strategies and impact on adherence and effectiveness.

SSI endpoints will be determined using the National Healthcare Safety Network (NHSN) SSI criteria.

**Intervention (if applicable):**

Intranasal PVI one time application (healthcare worker administered) just before surgery.

Intranasal mupirocin (patient administered) for 5 days before surgery.

Presurgical body bathing with CHG the night before and morning of surgery.

Presurgical body bathing with soap and water the night before and morning of surgery.

**Collaborators:**

Potential sites that we are in conversations with thus far:

UW-Madison

Advocate Health

University of Colorado

Denver VA

University of Maryland

Madison VA